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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

959 7590 09/22/2005

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,740	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9-14,17,25,26,28,29,31-33 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9-14,17,25,26,28,29,31-33 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-6, 9-14, 17, 25, 26, 28, 29, 31-33, and 39 are pending and under consideration in this Office Action.

2. The objection to claim 27 is moot and has been withdrawn in view of applicants' cancellation of claim 27 in the amendment filed 06/30/2005.

3. The objection to claim 33 for containing improper Markush language has been withdrawn in view of applicants amendment filed 06/30/2005, where the claim has been amended to recite the phrase "wherein the amino acid is selected from the group consisting of'.

4. The rejection of claims 1, 5, 6 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants amendment filed 06/30/2005, where the claims has been amended to recite the phrase "the complement thereof".

5. As previously noted the instant claims are granted the benefit of priority to June 23, 2000. The Examiner acknowledges applicants' statement in the amendment filed 06/30/2005 that the instant claims are granted priority of June 23, 2000, the filing date of the instant application.

6. The Examiner acknowledges applicants' request of foreign priority in the amendment filed 06/30/2005. However, as stated in the previous Office Action no certified copies of the German patent applications have been received. Thus, as previously noted foreign priority is not granted.

Claim Rejections - 35 U.S.C. § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 12-14 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 12-14, as written, do not sufficiently distinguish over cells as they exist naturally

because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105.

Furthermore, claim 12, as written, encompass naturally occurring whole organisms including humans, animals, plants as well as transgenic humans, animals, plants, all of which are non-statutory subject matter. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter.

The clams should be amended to recite the phrase "an isolated host cell transformed with the expression vector".

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 5, 6, 9-14, 17, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 which encodes a 6-phosphogluconolactonase, isolated host cell transformed with said vector, and a method for making a 6-phosphogluconolactonase encoded by SEQ ID NO: 1; does not reasonably provide enablement for any isolated nucleic acid encoding 6-phosphogluconolactonase which hybridizes to the complement of SEQ ID NO: 1 comprising hybridizing in 6X SSC at 45°C followed by washes in 0.2X SSC, 0.1% SDS at 50-60°C, any isolated nucleic acid molecule comprising a nucleotide sequence having at least 90% or 95% identity with SEQ ID NO: 1 which encodes a 6-phosphogluconolactonase or the complement thereof, and any host cell transformed with any vector comprising said nucleic acid which hybridizes to SEQ ID NO: 1 or said nucleic acid comprising a nucleotide sequence which has at least 90% identity to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed 06/30/2005 have been fully considered but they are not persuasive. Applicants' position is that in view of the Example 14 of the Written Description Guidelines making polypeptides which contain 5% variation from a specific sequence is routine in the art, the specification provides assays for identifying nucleic acids that have 90% or 95% identity to SEQ ID NO: 1 and encode 6-phosphogluconolactonase, and that the specification have defined particular hybridization conditions. The Examiner respectfully disagrees for the reasons of record as supplemented below.

The Written Description Guidelines provides guidance only for evaluating claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph. Thus, Example 14 of the Written Description Guidelines cannot be used in evaluating the instant claims for compliance with the enablement requirement of 35 U.S.C. 112, first paragraph. A separate analysis is required to determine whether the specification enables one skilled in the art to make and or use the claimed invention without undue experimentation.

As stated in the previous Office Action the specification and the prior art do not show any alignment of amino acid sequences of 6-phophogluconolactonases which indicate any conserved amino acid residues. The specification does not provide specific guidance, prediction, and working examples for the amino acids that can be changed without affecting enzyme activity. Thus, an undue amount of experimentation must be performed to search and screen for specific amino acids to change which do not affect enzyme activity and then make the corresponding encoding nucleic acid that is 90% or 95% identical to SEQ ID NO: 1. General teachings from the specification using enzyme assays to search and screen for the claimed invention is not guidance for making the claimed invention. In view of these considerations, the specification does not provide enablement for any nucleic acid molecule comprising a nucleotide sequence having at least 90% or 95% identity with SEQ ID NO: 1 which encodes a 6-phosphogluconolactonase or the complement thereof.

Regarding the hybridization conditions recited in claim 5, the specification does not provide guidance, prediction, and working examples regarding the specific nucleotide sequence of any nucleic acid molecule that will hybridize under the recited conditions and temperature range of 50-60°C to SEQ ID NO: 1. Thus, an undue amount of experimentation must be performed to search and screen for specific nucleic acid molecules that will hybridize to SEQ ID NO: 1 under the recited conditions and temperature range of 50-60°C and then search and screen for those nuclei acid molecules that will encode a functional 6-phosphogluconolactonase. Teaching regarding screening and searching for the claimed invention using enzyme assays stated in the specification is not guidance for making the claimed invention. In view of these considerations, the specification does not provide enablement for any isolated nucleic acid encoding 6-phosphogluconolactonase which hybridizes to the complement of SEQ ID NO: 1

comprising hybridizing in 6X SSC at 45°C followed by washes in 0.2X SSC, 0.1% SDS at 50-60°C

In regard to claim 12, the nature and breadth of the claim 12 encompass transgenic plants and animals including humans transformed with the claimed vector, where the vector comprises an isolated nucleic acid molecule comprising SEQ ID NO: 1. While the specification provides general guidance for transforming isolated *E.coli* host cells and isolated *C.glutamicum* host cells with the vector, the specification does not provide guidance, prediction, and working examples for making transgenic plants and animals including humans transformed with the claimed vector. Thus, an undue amount of trial and error experimentation must be preformed to make the claimed transgenic plants and animals including humans and determining whether the claimed vector expresses the claimed nucleic acid encoding 6-phosphogluconolactonase. In view of the above considerations, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the transgenic plants and animals including humans transformed with the claimed vector

11. Claims 25, 26, 28, 29, 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass methods for making a widely varying fine chemicals such as amino acids, nucleotides, aromatic compounds, vitamins, and proteins.

While the specification provides general guidance for transforming isolated *C. glutamicum* host cells with a vector containing the claimed insolated nucleic acid, the specification does not provide specific guidance, prediction, and working examples for any fine chemical that can be produced by culturing said isolated *C. glutamicum* host cells. Thus, an undue amount of trial and error experimentation must be preformed to search and screen for any fine chemical that can be produced by culturing the recited cell transformed with the claimed vector comprising the nucleotide sequence of SEQ ID NO: 1. Such experimentation is outside the realm of routine experimentation.

In view of the above considerations, the specification does not provide enablement for the claimed methods for making a widely varying fine chemicals such as amino acids, nucleotides, aromatic compounds, vitamins, and proteins.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 4-6, 9-14, 17, 25-29, 31-33, and 39 stand rejected under 35 U.S.C. 102(e) as being anticipated by Dunican et al. (US Patent 6,797,509).

Applicants' arguments filed 06/30/2005 have been fully considered but they are not persuasive. Applicants' position is that Dunican et al. fail to teach the nucleic acid molecules encoding having 6-phophogluconolactoanase activity as recited in the amended claims. The Examiner respectfully disagrees for the reasons of record as supplemented below.

As stated in the previous Office Action, Dunican et al. teach a 6995 base pair DNA sequence comprising that is 100% identical to SEQ ID NO: 1 of the claimed invention (see alignment attached to the Office Action dated 01/13/2005). The examiner takes the position that in absence of facts to the contrary the DNA taught by Dunican et al. would inherently encode a polypeptide having 6-phophogluconolactoanase activity since Dunican et al. teach a 6995 base pair DNA sequence that is 100% identical to SEQ ID NO: 1 of the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing the nucleic acid molecule comprising SEQ ID NO: 1 of the instant invention to the DNA sequence taught by Dunican et al., the burden is on applicants to show that the prior art DNA taught by Dunican et al. is different from the claimed nucleic acid molecule comprising SEQ ID NO: 1. See *In re Best*, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

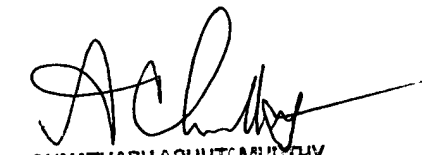
Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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